

JAN 26 2006

## 510(k) Summary

**Company:** Arthrex, Inc.  
1370 Creekside Blvd., Naples, FL 34108-1945  
**Telephone:** (239) 643-5553  
**Facsimile:** (239) 598-5508  
**Contact:** Ann Waterhouse

**Trade Name:** Arthrex Titanium and Bio-Degradable (polymer) Implants  
**Classification Name:** Fastener, Fixation, non-degradable and degradable  
**Regulation Number:** 21 CFR 888.3040 and 888.3030

### Device Description:

The Arthrex metal and polymer implants are manufactured from titanium alloy conforming to ASTM F136, and medical grade polymers (PLLA and PLDLA). These implant families are made up of previous cleared devices. The screws, anchors, suture taks, and buttons are threaded or smooth, fully cannulated, partially cannulated, or non-cannulated, and offered with or without suture. Most of these implants are offered for sale with specific instruments and accessories.

The Arthrex implants described above will now be sold sterile by VHP or Vaporized Hydrogen Peroxide. This method of sterilization does not compromise the integrity of the materials used in the construction of the Arthrex implants. The method of VHP sterilization has been validated to an SAL  $10^{-6}$ .

### Indications for Use:

Please reference the indications for use pages.

### Summary of Technologies:

The devices technological characteristics (materials, design, size ranges, and indications) are identical to those of the previously cleared products, and use similar or identical materials and packaging as that of the predicate devices.

### Non-Clinical Testing:

The following verification activities were performed on the implants which are the subject of this submission; Pull testing, shelf life, sterilization validation and microbiological testing.

### Substantially Equivalent Devices:

Arthrex is claiming substantial equivalence to sterilization processing of a competitor's products; Smith & Nephew hip (K012787), shoulder (K012788), and knee (K012778).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 26 2006

Ms. Ann Waterhouse  
Project Manager, Regulatory Affairs  
Arthrex, Inc.  
1370 Creekside Blvd.  
Naples, Florida 34108-1945

Re: K053338  
Trade/Device Name: Arthrex Titanium and Bio-degradable (Polymer) Implants  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC, MBI, MAI  
Dated: November 30, 2005  
Received: December 1, 2005

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

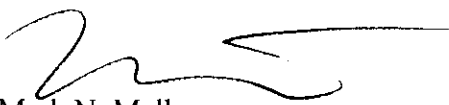
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain.

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Mark N. Melkerson  
Acting Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Bio-Interference Screw

Indications for Use:

The products found in the original 510(k) K971358 Bio-Interference Screw, will use the following indications for use:

- To provide interference fixation of bone-tendon-bone and soft tissue grafts in ACL reconstruction through arthroscopy or arthrotomy.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Page 1 of 6



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510(k) Number K053338

## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Bio-Transfix

Indications for Use:

The products found in the original 510(k) K011172 Bio-Transfix, will use the following indications for use:

- To provide ACL graft fixation in the femur in orthopedic procedures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Page 2 of 6

  
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510(k) Number K053338

## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Bio-FASTak and FASTak, Bio-Corkscrew and Titanium Corkscrew Suture Anchor

### Indications for Use:

The products found in the original 510(k) Arthrex FASTak Suture Anchor, K971723, K000506 Arthrex Bio-FASTak, K003227 Bio-Corkscrew Suture Anchor, and K003816 Titanium Corkscrew Suture Anchor are intended to fix suture to bone, and depending on size, will use the following indications for use:

*Shoulder:* Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

*Foot/Ankle:* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

*Knee:* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

*Elbow:* Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

*Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

*Pelvis:* Bladder Neck suspension for female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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Page   3   of   6  

510(k) Number   K053338

## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Tissue Tak Anchors

Indications for Use:

The products found in the original 510(k) K990340 Arthrex Tissue Tak, are intended for fixation of soft tissue to bone for reattachment of the glenoid labrum or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder in association with adequate post operative immobilization.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Page 4 of 6



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**510(k) Number** K053338

## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Tak Family

Indications for Use:

The products found in the original 510(k) K050749 Arthrex Tak Family are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and in select maxillofacial applications and will use the following indications for use:


- Skull:* Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and periorbital bones of the skull
- Elbow:* Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
- Shoulder:* Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Hand/Wrist:* Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers
- Foot/Ankle:* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
- Knee:* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Page 5 of 6

Division of General, Restorative,  
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510(k) Number K053338



## Indications for Use

510(k) Number (if known): K053338

Device Name: Arthrex Tenodesis Family

### Indications for Use:

The products found in the original 510(k), K051726 are intended to provide soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. This product is intended for the following indications:

*Shoulder:* Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

*Foot/Ankle:* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

*Knee:* Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

*Elbow:* Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

*Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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Page   6   of   6  

510(k) Number K053338